REMARKS

Claims 1-17 are pending in the instant application. Claim 6, 11-14, 16 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7-9 and 15 have been rejected. Claim 1 has been amended. Claim 3 has been canceled. New claims 18 through 21 have been added. Support for these amendments to claim can be found in the specification at page 14, lines 5-12, page 14, line 21 through page 17, line 2, page 33, lines 16-22, the mapping table at page 125-126 and the Sequence Listing. Thus, no new matter is added by this amendment.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed September 22, 2003. Thus, the Examiner has withdrawn from consideration claims 6, 10-14, 16 and 17 and nucleic acid sequences other than SEQ ID NO:24. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6, 10-14, 16 and 17. Further, Applicants have amended the claims to be drawn to the elected sequence SEQ ID NO:24 and its parent sequence SEQ ID NO:23. SEQ ID NO:23 exhibits significant homology with respect to SEQ ID NO:24 and identification of this parent sequence and its

utility as a lung cancer gene enabled Applicants to identify the longer sequence of SEQ ID NO:24. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Disclosure

The disclosure has been objected to for inclusion of embedded hyperlinks. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to inactivate any hyperlinks or other forms of browser executable code. In addition, Applicants corrected inadvertent typographical errors noted in these paragraphs upon amendment to inactivate the hyperlinks. No new matter has been added by this amendment. Withdrawal of this objection is respectfully requested in light of these amendments.

III. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7-9, and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Examiner regards as the invention.

Specifically, the Examiner suggests that the claims are

vague and indefinite for claiming more than was elected.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected SEQ ID NO:24 and its parent sequence, SEQ ID NO:23. Evidence of SEQ ID NO:23 being the parent sequence of SEQ ID NO:24 is provided at page 125, lines 30-31 of the instant specification.

Further, the Examiner suggests that recitation of "selectively hybridizes" in claim 1 is vague, indefinite and incomplete because the term is a relative term one and no frame of reference is given.

Applicants respectfully disagree since what is meant by "selectively hybridizes" is described in detail in the specification at page 14, lines 15-22. However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete this phrase and to clarify that the nucleic acid molecule is greater than 500 nucleotides as taught at page 33, lines 16-22 and hybridizes under stringent conditions. Further, Applicants have defined these conditions in accordance with teachings at page 14, line 21, through page 17, line 2.

The Examiner also suggests that recitation of "means for

determining the presence of the nucleic acid molecule of claim 1" in claim 15 is vague and indefinite because such means are not clearly defined.

Applicants respectfully disagree.

Exemplary means contemplated for determining the presence of a nucleic acid sequence are described in the patent application at page 95, line 31, through page 96, line 15.

MPEP § 2173 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. The content of the application in this case makes clear what is meant by stringent hybridization conditions and sets forth various means for detecting a nucleic acid in accordance with the claimed kits, thus meeting the requirements of 35 U.S.C. § 112, second paragraph. Further clarification in the claims is not required.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the above remarks and the amendments to the claims.

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

In particular, the Examiner suggest that part (c) of claim 1, drawn to nucleic acids which selectively hybridize to SEQ ID NO:24 and part (d) of claim 1, drawn to nucleic acids having at least 60% identity to said sequence cover a large genus of related nucleic acids which are not described and were not in applicants possession.

In addition, the Examiner has rejected claim 3 suggesting that the specification fails to describe the complete genomic DNA sequence corresponding to the cDNA of SEQ ID NO:24.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 3.

Applicants respectfully disagree with the Examiner's suggestion that the specification does not meet the written description requirements with respect to claim 1, part (c) and (d).

At the outset, it is respectfully pointed out that parts (c) and (d) have been amended and are now drawn to a nucleic acid

sequence greater than 500 nucleotides and hybridizing under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b) or a nucleic acid molecule having at least 96% sequence identity over its entire length to the nucleic acid molecule of (a) or (b). Support for these amendments are provided in the specification at page 14, lines 5-12, page 14, line 21 through page 17, line 2, and page 33, lines 16 through 22. Detailed methodologies for ascertaining sequences which meet these structural limitations of the instant amended claims are set forth in the specification at page 13, lines 7-26, and page 14, line 21 through page 17, line 2. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:24 and its parent sequence SEQ ID NO:23, applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public

in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 112, first paragraph

Claim 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 101 because the Examiner suggests that the claimed invention lacks patentable utility. The claims have also been rejected under 35 U.S.C. § 112, first paragraph as the Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Examiner suggests that the data presented in the case does not show a nexus between the presence or expression of SEQ ID NO:24 and lung cancer.

Applicants respectfully traverse these rejections.

The instant application claims the benefit of priority from U.S. Provisional Application Serial No. 60/252,055, filed

November 20, 2000 and U.S. Provisional Application Serial No. 60/252,496, filed November 22, 2000, the entire contents of which were incorporated by reference in their entirety into the instant application. See page 1, lines 4-7 of the instant application and the Preliminary Amendment filed February 20, 2002. In the priority application, parent sequence SEQ ID NO:23, referred to therein as SEQ ID NO:2 of U.S. Provisional Application Serial No. 60/252,469 (see page 125, lines 30-31 of the instant application), was demonstrated by suppression subtractive hybridization to be a lung cancer specific gene. These experiments described at pages 20 through 22 of the provisional application, which demonstrate utility of the instant claimed invention, have been incorporated into the instant application as Example 1a at page 118, line 28. No new matter is added by this amendment.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:23, the parent sequence of SEQ ID NO:24 as being a lung cancer specific gene constitutes a

pharmacological activity relevant to the asserted use as a diagnostic for lung cancer, thus satisfying the utility requirement.

Withdrawal of these rejections under 35 U.S.C. § 101 and 112, first paragraph is therefore respectfully requested.

VI. Rejection of Claims 1, 2, 4 and 5 under 35 U.S.C. § 102(b)

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by human EST Accession No. Al138780. The Examiner suggests that EST Accession No. Al138780 discloses a cDNA which has a region of 100% identity with SEQ ID NO:24 across a portion of about 28% of SEQ ID NO:24. Thus, the Examiner suggests that this EST cannot be distinguished from the instant invention because it would be expected to selectively hybridize to SEQ ID NO:24 and has at least 60% identity to SEQ ID NO:24. Further, the Examiner suggests that EST Accession NO. Al138780 is a cDNA and is human.

Applicants respectfully traverse this rejection.

As discussed in Section IV, supra, parts (c) and (d) of claim 1 of the instant application have been amended and are now drawn to a nucleic acid sequence greater than 500 nucleotides and hybridizing under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C

without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b) or a nucleic acid molecule having at least 96% sequence identity over its entire length to the nucleic acid molecule of (a) or (b). Support for these amendments is provided in the specification at page 14, lines 5-12, page 14, line 21, line 17 through page 17, line 2, and page 33, lines 16-22.

The sequence of EST Accession No. Al138780 of less than 500 nucleotides with a region of 100% identity with SEQ ID NO:24 across a portion of about 28% of SEQ ID NO:24 does not meet the limitations of the claims as amended.

Thus, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

VII. Rejection of Claims 1, 2, 4, 5 and 7-9 under 35 U.S.C. § 102(e)

Claims 1, 2, 4, 5, and 7-9 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Thompson et al. (U.S. Patent 6,428,994). The Examiner suggests that Thompson et al. discloses the cloning of a cDNA (SEQ ID NO:3) which has a region of about 76% identity with SEQ ID NO:24 across a portion of about 37% of SEQ ID NO:3. Thus, the Examiner suggests that the nucleic acid sequence of Thompson et al. cannot be distinguished from the instant invention because it would be expected to selectively

hybridize to SEQ ID NO:24 and has at least 60% identity to SEQ ID NO:24. Further, the Examiner suggests that the Thompson et al. sequence is a cDNA and is human and that this reference teaches a vector comprising the cDNA, a host cell comprising the vector and expression of an encoded protein using the host cell.

Applicants respectfully traverse this rejection.

As discussed in Section IV, supra, parts (c) and (d) of claim 1 of the instant application have been amended and are now drawn to a nucleic acid sequence greater than 500 nucleotides and hybridizing under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b) or a nucleic acid molecule having at least 96% sequence identity over its entire length to the nucleic acid molecule of (a) or (b). Support for these amendments is provided in the specification at page 14, lines 5-12, page 14, line 21, line 17 through page 17, line 2, and page 33, lines 16-22.

Accordingly, Thompson et al. which discloses the cloning of a cDNA (SEQ ID NO:3) which has a region of only about 76% identity with SEQ ID NO:24 across a portion of only about 37% of SEQ ID NO:3 does not meet the limitations of the claims as amended.

Thus, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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